K051463

JUL 12 2005

510(k) SUMMARY

NAME & ADDRESS: DENTSPLY International
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CONTACT: Helen Lewis

DATE PREPARED: May 26, 2005

TRADE OR PROPRIETARY NAME: XENO® ADHESIVE WITH ACTIVATOR

CLASSIFICATION NAME: Resin tooth bonding agent, 872.3200

PREDICATE DEVICES:
1) XENO® NM Light Cured Dental Adhesive, K041343
2) Prime & Bond® NT™ Dual Cure Nano-Technology Universal Dental Adhesive System, K050386

DEVICE DESCRIPTION: XENO® ADHESIVE WITH ACTIVATOR is a dual-cure, self-etch, two-component adhesive system. It utilizes the same XENO® adhesive found in the predicate and the same activator found in the Prime & Bond® NT™ adhesive system. When the self-etching adhesive is used in conjunction with the self-cure activator, it forms an adhesive layer that bonds to self-curing cements.

INTENDED USE: XENO® ADHESIVE WITH ACTIVATOR is indicated for direct, light-cured composite and compomer restorations; indirect restorations; light-cured resin cemented veneers; composite, ceramic, and amalgam repairs; cavity varnish for use with fresh amalgam; direct, dual-cure or self-cure composite restorations and core build-ups; resin cemented inlays, onlays, crown and bridge retainers, and endodontic post cementation; and adhesive bonding of direct amalgam restorations.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in XENO® ADHESIVE WITH ACTIVATOR have been used in legally marketed devices and were found safe for dental use. We believe that the prior use of the self-etching adhesive and the self-cure activator in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of XENO® ADHESIVE WITH ACTIVATOR for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K051463
Trade/Device Name: XENO® Adhesive with Activator
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: May 26, 2005
Received: June 03, 2005

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K051463

Device Name: XENO® ADHESIVE WITH ACTIVATOR

Indications for Use:

XENO® ADHESIVE WITH ACTIVATOR is indicated for:

- direct, light-cured composite and compomer restorations;
- indirect restorations;
- light-cured resin cemented veneers;
- composite, ceramic, and amalgam repairs;
- cavity varnish for use with fresh amalgam;
- direct, dual-cure or self-cure composite restorations and core build-ups;
- resin cemented inlays, onlays, crown and bridge retainers, and endodontic post cementation; and
- adhesive bonding of direct amalgam restorations.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Beltz DDS for Dr. S. Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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